Ketolac®

Tablets and ampoules I.M./ I.V.

Potent analgesic

Composition:

Each tablet contains :

Ketorolac tromethamine ..... 10 mg

Each 2 ml ampoule contains :

Ketorolac tromethamine ..... 30 mg

Properties:

- Ketorolac is a non-steroidal anti-inflammatory agent with a potent analgesic activity.
- Ketorolac acts through inhibiting prostaglandin biosynthesis. The drug is rapidly absorbed when given orally or intramuscularly; the peak plasma concentration is reached within 30 to 50 minutes of administration.

Indications:

Ketolac is used in the short term management of moderate to severe post-operative pain, arthritic pain, pain of trauma, cancer pain and severe dental pain.

Dosage and administration:

Intramuscularly:

Initially, 30 mg followed by 15 to 30 mg every 4 to 6 hours, up to a total daily dose of 90 mg for a maximum duration of 2 days.

Intravenously:

Ketolac is compatible with 5% glucose, 0.9% sodium chloride, ringer's injection, lactated ringer's injection or plasmolyte solution.

Orally:

10 mg every 4 to 6 hours preferably after meals, or with a glass of milk, to a maximum of 40 mg daily for a maximum duration of 7 days.

The combined daily dose for all forms of Ketorolac tromethamine should not exceed 90 mg daily except for elderly patients with mild renal impairment and in patients weighing less than 50 kg where the total dose should be reduced to 60 mg daily, of which not more than 40 mg should be given orally.

Adverse effects:

Adverse effects may be present in some cases as gastrointestinal pain, dyspepsia, nausea or peptic ulceration. Hypersensitivity reactions such as anaphylaxis, bronchospasm, laryngeal oedema or rash, may also occur. Other effects include drowsiness, dizziness and headache. There may be pain at the site of injection.

Precautions:

Liver function may change and the drug should be withdrawn if clinical symptoms of liver disease develop

Warning:

Ketorolac is not indicated to minor or chronic painful conditions. Ketorolac is a potent NSAID analgesic, and its administration carries many risks. Increasing the dose of ketorolac beyond the label recommendations will not provide better efficacy but will result in increasing the risk of developing serious adverse events.

Gastrointestinal effects:

Ketorolac can cause peptic ulcers, gastrointestinal bleeding and/or perforation. Therefore, ketorolac is contraindicated in patients with recent gastrointestinal bleeding or perforation, and in patients with a history of peptic ulcer disease or gastrointestinal bleeding.

Renal effects:

Ketorolac is contraindicated in patients with advanced renal impairment and in patients at risk for renal failure due to volume depletion.

Risk of bleeding:

Ketorolac inhibits platelet function and is, therefore, contraindicated in patients with suspected or confirmed cerebrovascular bleeding, patients with haemorrhagic diathesis, incomplete hemostasis and those at high risk of bleeding. Ketorolac is contraindicated as prophylactic analgesic before any major surgery and is contraindicated intraoperatively when hemostasis and those at high risk of bleeding.

Hypersensitivity:

Hypersensitivity reactions, ranging from bronchospasm to anaphylactic shock, have occured and appropriate counteractive measures must be available when administering the first dose of ketorolac. Ketorolac is contraindicated in patients with previously demonstrated hypersensitivity to ketorolac tromethamine or allergic manifestations to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs).

Labor delivery and nursing:

The use of ketorolac in labor and delivery is contraindicated because it may adversely affect fetal circulation and inhibit uterine contractions. The use of ketorolac is contraindicated in nursing mothers because of the potential adverse effects of prostaglandin-inhibiting drugs on neonates.

Contra-indications:

- Ketorolac is contraindicated in patients with active peptic ulcer disease, in patients with recent gastrointestinal bleeding or perforation and in patients with a history of peptic ulcer disease or gastrointestinal bleeding.
- Ketorolac is contraindicated in patients with advanced renal impairment or in patients at risk for renal failure due to volume depletion.
- Ketorolac is contraindicated in labor and delivery because, through its prostaglandin synthesis inhibitory effect, it may adversely affect fetal circulation and inhibit uterine contractions, thus increasing the risk of uterine hemorrhage.
- The use of Ketorolac is contraindicated in nursing mothers because of the potential adverse effects of prostaglandin-inhibiting drugs on neonates.
- Ketorolac is contraindicated in patients with previously demonstrated hypersensitivity to ketorolac tromethamine, allergic manifestation to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs).
- Ketorolac is contraindicated as prophylactic analgesic before any major surgery and is contraindicated intraoperatively when hemostasis is critical because of the increased risk of bleeding.
- Ketorolac is contraindicated in patients currently receiving ASA or NSAIDs because of the cumulative risk of inducing serious NSAID-related side effects.
- Ketorolac is contraindicated for neuraxial (intrathecal or epidural) administration due to its alcohol content.
- The concomitant use of Ketolac and probenecid is contraindicated.

Presentation:

Tablets: a box containing 20 tablets.
Ampoules: a box containing 5 ampoules, 2 ml each.

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